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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,655	08/31/2006	Kenneth Martin Taylor	110199.404USPC	5100

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EXAMINER	
NWAONICHA, CHUKWUMA O	
ART UNIT	PAPER NUMBER
1621	
MAIL DATE	DELIVERY MODE
08/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,655	TAYLOR ET AL.	
	Examiner	Art Unit	
	CHUKWUMA O. NWAONICHA	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *120-193* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *188-191* is/are allowed.

6)☒ Claim(s) *120-187,192 and 193* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Current Status

1. Claims 120-193 are pending in the application.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

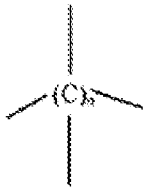
Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 130, 141 175 and 186 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 130, 141, 175 and 186 are indefinite because the structure of formula I is confusing. It is not clear if the structure shown below (which is part of formula I) represent a substituent: a methyl group or hydrogen. Clarification is required.



Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 128, 140, 158, 169-187 and 193 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specifically "a method of therapy of a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which comprises the step of administering to said patient an antioxidant compound and a method of preparing an antioxidant compound that is capable of reducing oxidative stress in a cell, comprising admixing cyclodextrin with a compound of the formula I" does not reasonably provide enablement for "a method of **prophylaxis** (**preventive**) of a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which comprises the step of administering to said patient an antioxidant compound and **derivative or derivatized as recited in claims 128, 140, 158, 174, 186 and 187**" as claimed.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The standard for determining whether the specification meets the enablement requirement is whether experimentation needed to practice the invention is undue or unreasonable. Accordingly, even though the forgoing statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be

enabled so that any person skilled in the art can make and use the invention without undue experimentation. See M.P.E.P. § 2164.

In the instant case, the claims cover "a method of **prophylaxis** (**preventive**) of a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which comprises the step of administering to said patient an antioxidant compound and **derivative or derivatized as recited in claims 128, 140, 158, 174, 186 and 187**".

Based on the above standards, the disclosure must contained sufficient information to enable one skilled in the pertinent art to practice this invention without undue experimentation. See M.P.E.P. 2164.01. Given the lack of disclosure of "a method of **prophylaxis** (**preventive**) of a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which comprises the step of administering to said patient an antioxidant compound and **derivative or derivatized as recited in claims 128, 140, 158, 174, 186 and 187**", the instant invention cannot be practiced commensurate in scope with the claims.

The Examiner understands that there is no requirement that the specification disclose every possible embodiment if there is sufficient guidance given by knowledge in the art (See M.P.E.P. § 2164.05(a)). However, the instant case goes beyond what is known in the art, because the specification does not offer any guidance on how one of ordinary skill would go about practicing the invention from the claim to "a method of **prophylaxis** (**preventive**) of a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which

comprises the step of administering to said patient an antioxidant compound and **derivative or derivatized as recited in claims 128, 140, 158, 174, 186 and 187**".

Here, the requirement for enablement is not met since the claims go far beyond the enabling disclosure. Based on the forgoing, **claims** 128, 140, 158, 169-187 and 193 are *prima facie* non-enabled for their full scope.

With regard to rejection under 35 U. S. C. 112, first paragraph, the following factors have been carefully considered (***In re* Wands**, 8 USPQ2d 1400; CAFC, 1988):

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

(1) **Nature of the invention.** As indicated above, the invention is drawn to "a method of **prophylaxis** (**preventive**) of a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which comprises the step of administering to said patient an antioxidant compound and **derivative or derivatized as recited in claims 128, 140, 158, 174, 186 and 187**".

(2) **Breadth of the Claim.** The claims are extremely broad. In particular, **claims** 128, 140, 158, 169-187 and193 that read on specifically "a method of **prophylaxis** (**preventive**) of a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which comprises the step of administering to said patient an antioxidant compound and **derivative or derivatized as recited in claims 128, 140, 158, 174, 186 and 187**".

(3) **Unpredictability of the Art.** The instant case is drawn to "a method of **prophylaxis** (**preventive**) of a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which comprises the step of administering to said patient an antioxidant compound and **derivative or derivatized as recited in claims 128, 140, 158, 174, 186 and 187**". A "method of **prophylaxis** (**preventive**) of a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which comprises the step of administering to said patient an antioxidant compound and **derivative or derivatized as recited in claims 128, 140, 158, 174, 186 and 187**" as claimed is speculative. Applicants' claim "a method of **prophylaxis** (**preventive**) of a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which comprises the step of administering to said patient an antioxidant compound and **derivative or derivatized as recited in claims 128, 140, 158, 174, 186 and 187**" is doubtful and requires objective proof. In such a speculative field, more enablement by way of specific examples is necessary in order to establish the utility of a genus. In re Fisher, 166 U.S.P.Q. 18.

(4) **Amount of Guidance Provided.** Applicants have provided guidance for "a method of therapy of a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which comprises the step of administering to said patient an antioxidant compound and and a method of preparing an antioxidant compound that is capable of reducing oxidative stress in a cell, comprising admixing cyclodextrin with a compound of the formula I". However, when

considering that the claims read on "a method of **prophylaxis** (**preventive**) of a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which comprises the step of administering to said patient an antioxidant compound and **derivative or derivatized as recited in claims 128, 140, 158, 174, 186 and 187**", it becomes critical to know how to make "**prevent** a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which comprises the step of administering to said patient an antioxidant compound and **derivative or derivatized as recited in claims 128, 140, 158, 174, 186 and 187**". This is critical to the practice of the invention and therefore should adequately be disclosed.

(5) **Ordinary Skill in the Art.** The ordinary skill artisan would not be able to practice the claimed invention with the current disclosure. It is not clear how to "**prevent** a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which comprises the step of administering to said patient an antioxidant compound and the **derivative or derivatized as recited in claims 128, 140, 158, 174, 186 and 187"** that applicant are claiming.

Thus, it can safely be concluded that the instant disclosure fails to provide an enabling disclosure for "a method of **prophylaxis** (**preventive**) of a patient suffering from or predisposed to Parkinson's disease, Alzheimer's disease, Huntington's Chorea, or Friedreich's Ataxia which comprises the step of administering to said patient an antioxidant compound and **derivative or derivatized as recited in claims 128, 140, 158, 174, 186 and 187"**.

The Examiner suggests that Applicants delete any subject matter that is not enabling.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 120, 121 and 127 are rejected under 35 U.S.C. 102(b) as being anticipated by Beg et al, {Spectroscopic studies of organophosphorus compounds, 1986, Pakistan J. of Scientific and Industrial Research, 29(3), 165-171, See abstract}.

Beg et al. disclose applicant's claimed antioxidant compound. See abstract.

Claims 120-185, 192 and 193 are rejected under 35 U.S.C. 102(b) as being anticipated by Murphy et al, {U.S. 6,331,532}.

Murphy et al. disclose applicant's claimed an antioxidant compound and its pharmaceutical composition. Columns 2, 3 and the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 120-185, 192 and 193 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,232,809. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patents, each taken individually, disclose a chemically stable antioxidant compound, its pharmaceutical composition, a method of reducing oxidative stress in a cell with a chemically stable antioxidant compound as defined by applicants' claims differing in specifics of arrangement to a degree that would have been obvious for one having ordinary skill in the art to form the purpose of achieving acceptable an antioxidant compound, its pharmaceutical composition, a method of reducing oxidative stress an antioxidant compound in order to arrive at applicants' claims with the expectation of success in the absence of a showing of new or unexpected result.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 120-185 and 192 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 120, 122-128 and 130-133 of copending Application No. 11/355,518 in view of Taylor et al. and claims 88-112 of copending Application No. 10/568,654 in view of Murphy et al. This is a provisional obviousness-type double patenting rejection.

The presently claimed chemically stable antioxidant compound, its pharmaceutical composition, a method of reducing oxidative stress in a cell with a chemically stable antioxidant compound is disclosed in the copending Application No. 11/355,518 and the copending Application No. 10/568,654.

Applicants claim a chemically stable antioxidant compound, its pharmaceutical composition, a method of reducing oxidative stress in a cell with a chemically stable antioxidant compound; wherein all the variables are as defined in the claims while the copending Application No. 11/355,518 and the copending Application No. 10/568,654 teach an antioxidant compound, its pharmaceutical composition, a method of reducing oxidative stress in a cell with an antioxidant compound; wherein all the variables are as defined in the claims. See claims 120, 122-128 and 130-133 of the copending

Application No. 11/355,518 and claims 88-112 of copending Application No. 10/568,654.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims overlaps substantially with the scope of claims 120, 122-128 and 130-133 of the copending Application No. 11/355,518 and claims 88-112 of copending Application No. 10/568,654, and the antioxidant compound, its pharmaceutical composition, a method of reducing oxidative stress in a cell with antioxidant compound in the copending Application No. 11/355,518 and claims 88-112 of copending Application No. 10/568,654 encompass the presently claimed invention. They differ in that Applicants claimed chemically stable antioxidant compound, its pharmaceutical composition, a method of reducing oxidative stress in a cell with a chemically stable antioxidant compound are broader in scope than the antioxidant compound, its pharmaceutical composition, a method of reducing oxidative stress in a cell with antioxidant compound in the copending Application No. 11/355,518 and the copending Application No. 10/568,654. This difference is not a patentable distinction because the copending Application No. 11/355,518 and the copending Application No. 10/568,654 teach the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill in the art.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to

identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 134 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 134 of Application No. 11/355,518. This is a double patenting rejection.

Allowed Claims

Claims 188-191 are allowable over the prior art of record.

Reason For Allowance

The following is an examiner's statement of reasons for allowance: A search of the prior art failed to uncover any reference that anticipates or renders obvious a method of synthesis of a compound having the formula III or its quinol form; wherein all the variables are as defined in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is 571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chukwuma O. Nwaonicha/

Examiner, Art Unit 1621

/Sikarl A. Witherspoon/
Primary Examiner, Art Unit 1621

(for)

Daniel Sullivan
Supervisory Patent Examiner,
Art Unit 1621